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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,502	02/22/2002	Jeffrey L. Cleland	10466/286	8669

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EXAMINER	
AZPURU, CARLOS A	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,502	CLELAND ET AL.	
	Examiner	Art Unit	
	Carlos A. Azpuru	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25 and 29-52* is/are rejected.

7)☒ Claim(s) *26-28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the request for continued examination and amendment filed 01/26/2006.

The rejection under 35 USC 102(b) over Domb et al is hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 13-20, 23, 24, and 29-40, 41-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 7 has been amended to include the phrase "having a diameter smaller than that of a 20 gauge needle". The original specification does not support this. The original specification at page 5, line 11 states, "no greater than that of a 20 gauge needle". This statement clearly includes 20 gauge as its upper limit. At page 14, line 8 applicant clearly states that the invention may be used in a 20 gauge needle. As such, the language added to claim 7 is considered new matter.

Claims 8, 13, 23 and 34 include the language "less than 200 centipoise". The written description does not support this limitation. At page 14, line 18, applicant clearly states "the viscosity of the liquid is preferably at most 2000 centipoise, including 2000-50 centipoise." The range of viscosity clearly includes the upper limit of 2000 centipoise.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-25, 29, 33- 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Merck & Co, Inc (WO'073).

WO'073 disclose a liquid polymeric composition for controlled release of a bioactive which comprises a solvent mixture of a hydrophobic solvent and a hydrophilic solvent, a bioerodible polymer, and a drug (see Abstract). The bioerodible nature of the polymers is disclosed at page 9, line 28. The composition is specifically recited for its lack of burst effect. The ratio of hydrophilic to lipophilic solvent is from about 80:20 to about 0:100 (see page 7, line 11). At page 8, lines 9-13, the ingredients are mixed with dissolving of both the polymer and bioactive, with suspensions and encapsulation (gels) being less preferable, but within the scope of the invention. At page 15, lines 5-8, solutions and suspensions are specifically recited. The limitation of "solution, suspension or gel" is therefore met. The drug is found at a concentration of 1-30% (see

page 1, line 22). The limitation of subsequent injection through a needle of specified size is considered an intended use for a composition. Less than 25% of the beneficial agent is released at 24 hrs as can be seen by Figure 1. The patent also discloses that the rate of initial drug delivery are controlled by the proportions of the hydrophilic and lipophilic solvents at given polymer and drug concentrations (See page 27, lines 24-26). Since each of these parameters is anticipated by the patent, the rate of the initial drug delivery would inherently also be anticipated. Polylactides, polyglycolides and their copolymers are specifically disclosed at page 10, lines 9 and 10. C6 Alkanols are specifically recited as hydrophilic solvents and include benzyl alcohol at page 10, lines 17-32. Hydrophobic solvents include benzyl benzoate at page 11, line 1. The viscosity range of less than 2000 centipoise is inherent to the composition since it is disclosed to have the same constituents, used for the same art recognized purpose, and administered in the same way. The solubility of the hydrophobic solvent is inherent to the solvents used, and is also disclosed as less than 1% at page 26, line 26. Peptides and proteins are recited for use in the drug delivery system at page 23, lines 7-27. Administration by syringe is recited at page 25, line 10. This would qualify as a container as well in the kit. Unit dosage is described at page 25, lines 16-17. Any drug delivery system or depot administered to the body is inherently sterile since infections are not desired. A syringe inherently has a septum as part of its plunger system. Depots formed form the composition are discussed at page 27, lines 17-22. The instant claims are therefore anticipated by WO'073.

Claims 26-28 are objected to as dependent upon a rejected base claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Carlos A. Azpuru
Primary Examiner
Art Unit 1615

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